

PRIA Renegotiation Form

Decision	Registration Number	Petition
549334	42750-GLO	

Chemical Name	Flucarbazone-sodium Technical
Company Name	ALBAUGH, LLC
Fee Category	R333
PRIA Decision Time Frame	10M
Original PRIA Due Date	2020-02-04
Proposed New PRIA Due Date	2020-05-04
Current and Previous Negotiated Dates	

Negotiated Due Date Reason

Additional Data Required:	
<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Toxicology <input type="checkbox"/> Acute Tox <input type="checkbox"/> Environmental <input type="checkbox"/> Efficacy <input type="checkbox"/> Ecological <input type="checkbox"/> Residue <input type="checkbox"/> Other	
Comments:	

Data Deficiencies:	
<input type="checkbox"/> Product Chemistry <input type="checkbox"/> Toxicology <input type="checkbox"/> Acute Tox <input type="checkbox"/> Environmental <input type="checkbox"/> Efficacy <input type="checkbox"/> Ecological <input type="checkbox"/> Residue <input type="checkbox"/> Labeling <input type="checkbox"/> Other <input type="checkbox"/> Not Submitted	
Comments:	

Late Risk Assessment:	
<input type="checkbox"/> Human Health <input type="checkbox"/> Ecological	

Interim Considerations:	
<input type="checkbox"/> Agency Initiated <input type="checkbox"/> Registrant Initiated	

☐ 11-3 Deficiencies need to be addressed
 ☐ Endangered Species Concerns
 ☐ Data Not Submitted
 ☐ Failure to Respond to Deficiencies
 ☐ Other - Comment Field
 ☐ Risk Issues Environmental
 ☐ Risk Issues Human Health
 ☐ CSF
 ☐ Label
 ☐ Public Process
 ☐ Impurities Review
 ☐ Administrative-FR Notice
 ☒ Other - No Reason Selected in Webform

Summary of Deficiency Type(s)

☐ Agency Initiated
 ☐ Registrant Initiated

Is "Fix" in-house? NA

Describe Interactions with Company(Describe when Contacted and Company's Response including response to Previous Negotiated Due Dates:)

On January 6, 2020 the registrant, Albaugh LLC, was informed that the product chemistry review was not yet complete and more time would be needed. On January 9, 2020 Albaugh LLC requested a new PRIA date of May 4, 2020. This action was not included in a formal submission of priorities made by this registrant to the RD Division Director.

"75 Date" Letter Sent?

No

Reason for None

na

Registrant Notified that this is the Last Negotiation?

NA

Rationale for Proposed Due Date: The product chemistry review has not yet been scheduled by CITAB. Therefore, this renegotiation is requested to offer more time for completion of that review as well as other review necessary to complete this action.

Issue(s) Describe in Detail: The product chemistry bean was sent to CITAB on 4/22/2019. The original last science due date for product chemistry was 12/6/2019. Due to human resource limitations, the product chemistry review will not be completed in time to meet the current PRIA date. The Registration Division is working on ways to address backlog including working on company high priority actions, working with product teams to identify critical needs, and training staff outside of CITAB to complete less complex reviews.

Comment(s):

Approved
/Disapproved:

Approved

Date of Final Decision	Thu Jan 16 15:24:37 EST 2020 Richard Keigwin (RKEIGWIN) from IO (Host IP Address: 10.202.148.182)
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e-Signature:

Richard Keigwin (RKEIGWIN) from IO (Host IP Address: 10.202.148.182)